

**REMARKS**

The Amendment, filed in response to the Office Action mailed March 30, 2010, is believed to fully address all and every issue raised in the Office Action. Favorable reconsideration on the merits and allowance of the application are respectfully requested.

***Disposition of Claims and Claim Amendments***

In the Office Action, claims 1-17 were all the claims pending in the application. Claims 16 and 17 have been withdrawn from consideration as being directed to non-elected subject matter. Claims 1-15 have been considered and rejected.

In the instant Amendment, claim 1 is amended to incorporate the limitations of claims 8 and 12, and claims 8 and 12 are canceled. Claims 9, 10, and 13 are amended to amend dependency according to the cancellation of claims 8 and 12.

No new matter is introduced. Entry and consideration of the Amendment are respectfully requested.

***Restriction Requirement***

In response to the Examiner's Restriction Requirement to elect a single invention from Group I, claims 1-15 and Group II, claims 16-17, Applicants affirm the election of Group I, claims 1-15, which was made at the telephone conversation on February 17, 2010.

Applicants respectfully submit that if elected claims are found allowable, any claims containing all the limitations of the allowable claims be rejoined for consideration.

Applicants reserve right to file a divisional application directed to non-elected subject matter.

***Response to Specification Objection***

In the Office Action, the specification is objected to because it contains the trademark ZOCOR (pages 18-19) and the term “xanthan gum” is incorrectly spelt as xantan gum on at least pages 7-8.

In response, Applicants amend the above-listed items throughout the specification, rendering the objection moot.

Withdrawal of the objection is respectfully requested.

***Response to Claim Rejections - 35 USC § 103***

***1. Rejections of claims 1-7 and 15 based on Gutierrez-Rocca***

At page 7 of the Office Action, claims 1, 3-7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutierrez-Rocca et al. (US Patent No. 6524615).

At page 10 of the Office Action, claim 2 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Gutierrez-Rocca et al, in view of Serajuddin et al. (US Patent No. 5433951).

In response, without conceding the rejection, solely for the interests of Applicants to advance the prosecution, Applicants amend claim 1 to incorporate the limitation of claims 8 and 12, rendering the rejection over Gutierrez-Rocca moot.

Therefore, withdrawal of the rejections of claims 1-7 and 15 under 35 U.S.C. § 103 over Gutierrez-Rocca, either alone or combined with Serajuddin is respectfully requested.

2. Rejection of claims 8-14 based on Gutierrez-Rocca and Baichwal & Rejection of claims 1, 3-4 and 7-15 based on Louie-Helm and Baichwal

At page 12 of the Office Action, claims 8-14 rejected under 35 U.S.C. § 103(a) as being unpatentable over Gutierrez-Rocca et al, in view of Baichwal et al. (US Patent No. 5135757) as evidenced by Mosquera et al. (Int. J. Pharmaceutics, 1996).

At page 16 of the Office Action, claims 1, 3-4 and 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louie-Helm et al. (USPGPUB No. 20030091630) in view of Baichwal et al.

Applicants respectfully traverse the rejection for the following reasons.

**(1) Technical Features of the Subject Invention**

The subject invention defined in pending independent claim 1 relates to a sustained release formulation for oral administration of an HMG-CoA reductase inhibitor comprising a solid dispersant containing an HMG-CoA reductase inhibitor, a solubilizing agent and a stabilizing agent; a sustained release composite carrier; and a gel hydration accelerator, wherein the sustained release composite carrier is a mixture of sodium alginate and xanthan gum, and the gel hydration accelerator is a mixture of propylene glycol ester alginate and hydroxypropyl methyl cellulose.

The subject invention provides a sustained release formulation for oral administration of an HMG-CoA reductase inhibitor for treating hyperlipidemia which is capable of slowly releasing the HMG-CoA reductase inhibitor at a uniform rate for a long time.

Further, the formulation of the subject invention is prepared not by simply mixing together an HMG-CoA reductase inhibitor, a solubilizing agent, a stabilizing agent, a sustained

release composite carrier and a gel hydration accelerator, but by a two-step process comprising mixing the HMG-CoA reductase inhibitor, a solubilizing agent, and a stabilizing agent to form a solid dispersant first, and then adding a sustained release composite carrier and a gel hydration accelerator thereto.

## **(2) Summary of the Cited References**

By way of review, Gutierrez-Rocca relates to a sustained release pharmaceutical dosage form comprising (a) a water insoluble medicament, (b) a high melting fatty ester, (c) a low viscosity oil, (d) a cellulose polymer, and (e) a non-ionic surfactant.

Baichwal discloses a universal tableting granulated excipient which is free-flowing and directly compressible for a controlled release of a relatively soluble or insoluble therapeutically active medicament. The excipient comprises heteropolysaccharide (e.g., xanthan gum), a cross-linking agent capable of cross-linking said heterosaccharide (e.g., locust bean gum), and an inert filler (e.g., lactose).

Louie-Helm discloses an erodible, gastric-retentive drug dosage form comprising the pharmaceutically active agent incorporated in a matrix of at least one biocompatible, hydrophilic polymer such as cellulosic polymer, polysaccharide gum, and naturally occurring hydrophilic polymer.

## **(3) Comparison of the Subject Invention with the Cited References**

**3-1: Gutierrez-Rocca, Baichwal, and Louie-Helm, either alone or combinations, fail to teach all and every limitations of currently amended independent claim 1.**

The Examiner pointed out that Gutierrez-Rocca discloses a sustained release pharmaceutical dosage form comprising an HMG-CoA reductase inhibitor (atorvastatin,

simvastatin, lovastatin, etc.), carrier (a high melting fatty ester and a low viscosity oil), a gel hydration accelerator (a cellulose polymer), and a solubilizing agent (a non-ionic surfactant).

However, Gutierrez-Rocca fails to disclose a solid dispersant containing an HMG-CoA reductase inhibitor, a solubilizing agent and a stabilizing agent, which is prepared before adding a sustained release composite carrier and a gel hydration accelerator thereto, and, further, neither of Baichwal or Louie-Helm teaches the unique constitution, i.e., the solid dispersant.

In addition, Gutierrez-Rocca also fails to disclose or suggest a mixture of sodium alginate and xanthan gum as a sustained release composite carrier, and a mixture of propylene glycol ester alginate and hydroxypropyl methyl cellulose as a gel hydration accelerator.

### **3-2. Claimed subject matter shows unexpected remarkable effects**

Moreover, the subject formulation exhibits markedly improved water-solubility, stability and bioavailability. To further demonstrate the remarkable effects of the subject invention, Applicants submit an executed declaration in accordance with 37 C.F.R. section 1.132 together with this response.

As can be seen from the Declaration, the subject invention shows markedly improved solubility, bioavailability, and stability over the corresponding formulation without the solid dispersant.

As stated above, the unique technical feature of the solid dispersant of the subject invention cannot be preconceived based on the cited references, and markedly improved effects of the formulation of the subject invention have never been achieved in the past.

Accordingly, currently amended claim 1 is patentable over the cited references. Withdrawal of the rejection is respectfully requested.

***Response to Obviousness Rejection Over Copending Application No.10650931***

At page 20 of the Office Action, claims 1 and 3-15 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10650931 (Woo et al., PGPUB No. 20040081693) which has a common inventor with the instant application in view of Gutierrez-Rocca.

In response, Applicants first note that the Examiner's intention was to reject claims 1 and 3-15 under 35 U.S.C. §103(a) or 35 U.S.C. § 103(c), because Woo was published before the filing date (April 28, 2005, which is the international filing date of the instant application), but after the foreign priority date (April 10, 2004) of the instant application.

Applicant respectfully traverse.

Woo is silent about the feature of the instantly claimed subject matter, i.e., "solid dispersant." Gutierrez-Rocca fails to cure the defect.

Therefore, the combined teaching of Woo and Gutierrez-Rocca fails to teach all and every limitation of currently claimed subject matter. Withdrawal of the rejection is respectfully requested.

***Response to Provisional Rejection of Obviousness-Type Double Patenting***

At page 24 of the Office Action, claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-6, 8 and 10 of copending Application No. 10650931 in view of Gutierrez-Rocca et al. Although the

conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

In response, Applicants first note that the copending '931 has been issued into patent No. 7,704,526 on April 28, 2010.

With regard to the merits, Applicants respectfully traverse.

As discussed above, copending '931 application, either or alone fails to teach the feature of the subject invention, i.e., the solid dispersant, recited in claim 1.

Accordingly, it is respectfully submitted that the double patenting rejection of claims 1 and 15 be withdrawn.

### ***132 Declaration Submission***

Applicants submit a copy of Declaration under 37 C.F.R. 1.132, executed by Si Young Jung, as co-inventor, under a separate cover letter. Entry and consideration are respectfully requested.

### **Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number **202-775-7588**.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Sunhee Lee/

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

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Sunhee Lee  
Registration No. 53,892

WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: June 30, 2010

**Attachment: 132 Declaration (under separate cover)**